UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

ARTHREX, INC.

Plaintiff,

v. Case No: 2:22-cv-19-JLB-NPM

PARCUS MEDICAL, LLC and ANIKA THERAPEUTICS, INC.

Defendants.

ORDER

This case involves two patents related to ankle repair. Before the Court are the parties' claim construction briefs: Plaintiff Arthrex, Inc.'s opening and reply briefs, (Doc. 55, Doc. 57), and Defendants Parcus Medical, LLC and Anika Therapeutics, Inc.'s (collectively "Defendants") opening and reply briefs, (Doc. 56, Doc. 58). On December 1, 2022, the Court held a Technology Tutorial and Claim Construction hearing during which the Court heard argument from both sides as to how six disputed limitations in the two patents should be construed. This Order addresses those proposed constructions.

BACKGROUND

Arthrex is the owner and assignee of the '686 and '028 Patents. (Doc. 54-5; Doc. 54-7.) The '686 Patent was filed on October 15, 2015, and the '028 Patent was filed on February 19, 2020. (*Id.*) Both the '686 Patent and the '028 Patent are directed towards methods of ankle syndesmosis repair. (Doc. 54-5 at 19; Doc. 54-7

at 19.) Syndesmosis injuries affect the "strong fibrous ligaments" that stabilize the ankle joint. (*Id.*) Ankle syndesmosis repair helps to fix ankle injuries involving a disruption of the ligaments, which hold the tibia and fibula together and prevent the ankle joint from becoming unstable. (*Id.*)

Past methods of performing ankle syndesmosis repair—such as the one recited in the '091 Patent referred to *infra*—required the tying of knots to secure surgical buttons against the tibia and fibula. (*Id.*) The two patents in this case allege to improve upon the prior art by providing "[a]n ankle syndesmosis repair construct and technique . . . which provides the same fixation as disclosed in the ['091] patent, but without the need for tying knots." (*Id.*)

The inventions allow for the stabilization of the ankle bones via a knotless loop construct including two fixation devices—likely surgical buttons—and at least one loop, made of flexible material, attached to the two fixation devices. (Doc. 54-7 at 20; Doc. 54-5 at 20.) In an exemplary embodiment[1], flexible material, which forms the loop, is threaded through the eyelets of the two fixation devices to create a

[1] The precise language used in the '028 and '686 Patents is:

> In an exemplary and illustrative embodiment only, self-locking, knotless, adjustable button / loop construct includes buttons and flexible material with two adjustable eyesplices that are interconnected to form one adjustable loop. By pulling on the free braid strands, the individual eyesplices constrict and, in turn, reduce the loop length of the loop. Elongation of loop is prevented because for loop to elongate, a force must be applied interior to one or both of the eyesplices to elongate the individual loops.

(Doc. 54-5 at 21; Doc. 54-7 at 21.)

knotless, self-cinching repair system. (*Id.*) The process of tightening the second fixation device against the lateral fibular cortex—the side of the fibula bone, which does not face the tibia—involves pulling a free strand of the flexible material to tug in the fixation device and affix it on the bone. (*Id.*) The process is knotless because splices prevent the adjustable loop from loosening in the direction opposite of the direction in which the free strand is being pulled. (*Id.*) The tension on the flexible material causes the loop to automatically lock in place, holding the tibia and fibula together and facilitating repair. (*Id.*) This process is referred to in both patents as the "self-locking" feature of the adjustable suture construct. (*Id.*) Figure 16, below, is illustrative of both the elements and design of the suture construct, and Figure 20, below, demonstrates the way the suture construct fits onto the tibia and fibula.

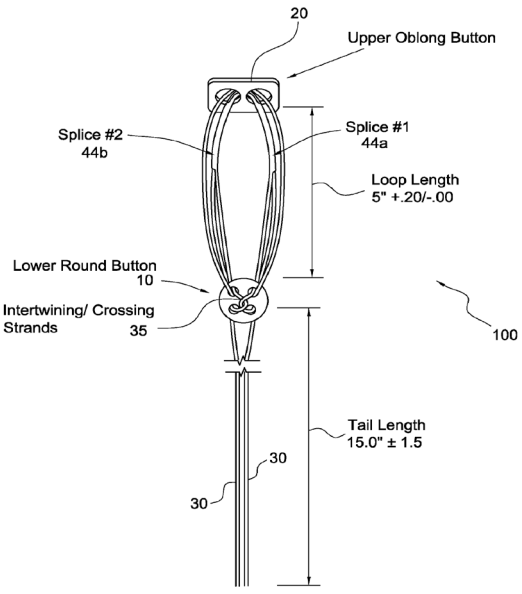

FIG. 16

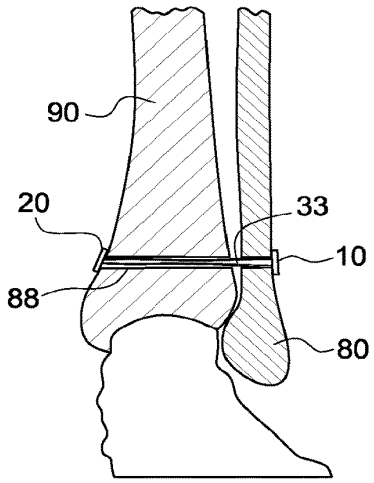

FIG. 20

(Doc. 54-5 at 11–12; Doc. 54-7 at 11–12.)

The six disputed claim terms describe various portions of the method of ankle syndesmosis repair outlined above.

LEGAL STANDARD

Claim construction is "exclusively for the court to determine." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015) (quotation omitted). The words of a claim "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005); *Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1347 (Fed. Cir. 2014) ("There is a heavy presumption that claim terms carry their accustomed meaning in the relevant community at the relevant time."). The plain and ordinary meaning of a term is the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313. The person of ordinary skill in the art ("POSA") is considered to have read the claim term in the context of the entire patent. *Id.*

Claims must also be read "in view of the specification, of which they are a part." *Forest Lab'ys, LLC v. Sigmapharm Lab'ys, LLC*, 918 F.3d 928, 933 (Fed. Cir. 2019). "[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quotation omitted). In the specification, a patentee may act as a lexicographer and define a term to have a meaning that differs from the meaning that the term would otherwise possess. *Id.* at 1316. The specification may also reveal a patentee's intent to disavow claim scope. *Id.* In

either case, the patentee's lexicography or disavowal governs, and the plain meaning of the term is not to be applied. *Id.* Although the specification may suggest that a certain embodiment is preferred, a particular embodiment appearing in the specification will not be read into the claim when the claim language is broader than the embodiment. *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

The prosecution history is another tool to supply the proper context for claim construction because it shows how the inventor understood the terms. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (explaining that the prosecution history "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the [PTO] is often of critical significance in determining the meaning of the claims."). Further, "[t]he prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

"In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." *Vitronics*, 90 F.3d at 1583; *see also Southwall*, 54 F.3d at 1578 ("A patentee may not proffer an interpretation for the purposes of litigation that would alter the indisputable public record consisting of the claims, the specification and the prosecution history, and treat the claims as a 'nose of wax.'").

The Court proceeds with these principles in mind.

DISCUSSION

Before turning to the construction of the six disputed claims, the Court turns to an overarching dispute that the parties have presented for the Court's consideration, namely, whether two claim terms—which the parties have designated as Claim Terms #2 and #4—are drafted in a step-plus-function format, which is governed by 35 U.S.C. § 112(f); *see Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012) ("Whether a claim complies with the definiteness requirement of 35 U.S.C. § 112 is a matter of claim construction."). Arthrex argues that Section 112(f) does not apply to either claim term, and Defendants argue that Section 112(f) applies to both claim terms. (*See* Doc. 55 at 18–19, 22–24; Doc. 56 at 15–20, 25–29.)

35 U.S.C. § 112(f) provides:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

See 35 U.S.C. § 112(f).

"It is well established that this statutory provision can apply not only to a combination of mechanical elements, but also to a combination of steps in a process." *Masco Corp. v. U.S.*, 303 F.3d 1316, 1326 (Fed. Cir. 2002). As the Federal Circuit has explained, Section 112(f) "is implicated only when steps *plus function* without acts are present. The statute thus in effect provides that an element in a

combination method or process claim may be recited as a step for performing a specified function without the recital of acts in support of the function." *O.I. Corp. v. Tekmar Co. Inc.*, 115 F.3d 1576, 1583 (Fed. Cir. 1997). If Section 112(f) is implicated, the limitation must be construed "to cover the corresponding . . . acts described in the specification." 35 U.S.C. § 112(f).

Courts presume that Section 112(f) applies in the context of method claims where the limitation uses the phrase "steps for." *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996). If the limitation does not use the phrase "steps for," then a rebuttable presumption is created that Section 112(f) does not apply. *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998); *Seal-Flex, Inc. v. Athletic Track & Court Const.*, 172 F.3d 836, 848 (Fed. Cir. 1999) (J. Rader concurring).

The rebuttable presumption can be overcome, however, if the party asserting that Section 112(f) applies demonstrates that the claim term does not recite any specific acts. *Seal-Flex*, 172 F.3d at 848; *Masco*, 303 F.3d at 1327 (holding that "where a method claim does not contain the term 'step[s] for,' a limitation of that claim cannot be construed as a step-plus function limitation without a showing that the limitation contains no act."). The Federal Circuit has cautioned that it is "unwilling to resort to [Section 112(f)] to constrain the scope of coverage of a claim limitation without a showing that the limitation contains nothing that can be construed as an act." *Masco*, 303 F.3d at 1327. To determine whether a claim element can be construed as an act, courts look to how the steps of the asserted

method are to be implemented because acts correspond to *how* the function is accomplished. *O.I. Corp.*, 115 F.3d at 1583.

Merely claiming a step by itself, or a series of steps, does not implicate Section 112(f). *O.I. Corp.*, 115 F.3d at 1583; *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371, 1382 (Fed. Cir. 2004) (observing that a method claim "necessarily recite[s] the steps of the method"). But if a claim term recites a step that is individually associated with a specified function, Section 112(f) will be implicated, *if* that element does not also recite the act necessary to perform the step and achieve the function. *Epcon Gas Systems, Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1028 (Fed. Cir. 2002); *Dynamic Digital Depth Rsch. PTY LTD v. LG Elecs., Inc.*, No. CV 15-5578-GW(EX), 2016 WL 7444569, at *11 (C.D. Cal. Nov. 7, 2016) ("A claim element that does not recite express step-plus-function language may nevertheless be a step-plus-function limitation if it recites only an underlying function without acts for performing it."). Stated in the alternative, "[i]f the Court does find an act [in the claim term], then . . . [Section 112(f)] does not apply." *Neurografix v. Regents of Univ. of California*, No. 2:11-CV-07591-MRP-RZ, 2012 WL 8281409, at *6 (C.D. Cal. June 13, 2012). And "step-plus-function limitations are not an often used limitation." *Dynamic Digital*, 2016 WL 7444569, at *11.

Here, because the disputed claim terms do not use the phrase "step for," a rebuttable presumption exists that Section 112(f) does not apply. *Masco*, 303 F.3d at 1327. Furthermore, the Court notes that the United States Patent & Trademark Office examiners failed to find that a POSA would understand either claim term to

be governed by Section 112(f) in either the '028 or the '686 Patents. (*See* Doc. 57 at 10; Doc. 54-6; Doc. 54-8); *see also Manual of Patent Examining Procedure* § 2818 (9th ed., June 2020) (providing that "[a] determination that a claim is being interpreted according to 35 U.S.C. 112(f) should be expressly stated in the examiner's Office action"). While the USPTO's failure to find that Section 112(f) applies is not binding on the Court, it is certainly instructive given the thoroughness and specialized knowledge with which the USPTO undertakes patent examinations. *See SKF Condition Monitoring, Inc. v. SAT Corp.*, No. 07CV1116BTMNLS, 2008 WL 706851, at *7 (S.D. Cal. Feb. 27, 2008) (finding that the USPTO's "expert evaluation" and "understanding of the claims" is "also likely to aid this Court in the preliminary process of claim construction").

In light of the rebuttable presumption against the applicability of Section 112(f), the Court's task is to determine whether the claim terms are steps-plus-function limitations, and if so, whether the terms recite any specific acts. *Masco*, 303 F.3d at 1327. Again, "[i]f the Court does find an act [in the claim terms], then . . . [Section 112(f)] does not apply." *Neurografix*, 2012 WL 8281409, at *6. Defendants argue that each claim term recites a function, but neither claim term recites an act to perform the specified function. (Doc. 56 at 18, 28.) Instead, Defendants argue that the specified functions correspond to what the elements ultimately accomplish, rather than the specific procedure by which they are accomplished. (*Id.* at 18–19, 28–29.)

i. Whether Section 112(f) Applies to Disputed Claim Term #2

The Court first turns to Claim Term #2, which states, "wherein the first fixation device and the second fixation device are knotlessly secured relative to the tibia and fibula." (Doc. 53-1 at 3.) The term appears in claim 1 of the '028 Patent in the following context: "A method of ankle syndesmosis repair, comprising: . . . positioning a second fixation device at a lateral side of the fibula, *wherein the first fixation device and the second fixation device are knotlessly secured relative to the tibia and the fibula*." (Doc. 54-7 at 22–23.) The question for the Court is first, whether "knotlessly secured" is a function, and if so, whether an act can be found in the disputed claim term, which would accomplish the function of "knotlessly secured." *See Masco*, 303 F.3d at 1327.

As stated above, "[a] claim element that does not recite express step-plus-function language may nevertheless be a step-plus-function limitation if it recites only an underlying function without acts for performing it." *Dynamic Digital*, 2016 WL 7444569, at *11. In his concurrence in *Seal-Flex*, Judge Rader outlined the difference between an "act" and an "underlying function" stating:

> In general terms, the "underlying function" of a method claim element corresponds to *what* that element ultimately accomplishes in relationship to what the other elements of the claim and the claim as a whole accomplish. "Acts," on the other hand, correspond to *how* the function is accomplished. Therefore, claim interpretation focuses on what the claim limitation accomplishes, i.e., its underlying function, in relation to what is accomplished by the other limitations and the claim as a whole. If a claim element recites only an underlying function without acts for performing it, then [Section 112(f)] applies even without express step-plus-function language.

172 F.3d at 849–50 (J. Rader concurring).

With Judge Rader's instructions in mind, the Court finds that "knotlessly secured" is not an underlying function. In the context of Claim 1, "knotlessly secured" is deployed as a past participle—specifically, "the [fixation devices] are knotlessly secured." Rather than reciting a function to be performed, "knotlessly secured" appears to be a description of how the first and second fixation devices interact with the tibia and fibula at the point that they are being "position[ed]." (*See* Doc. 54-7 at 23.) The claim term therefore does not recite a step-plus-function because it does not contain functional language, nor is anything in the method being accomplished by virtue of being "knotlessly secured." *See Seal-Flex*, 172 F.3d at 849 (explaining that "functions are often stated using verbs ending in 'ing'" and the "the 'underlying function' of a method claim element corresponds to *what* that element ultimately accomplishes in relationship to what the other elements of the claim and the claim as a whole accomplish").

Section 112(f) is implicated only when steps, *plus function*, without acts are present, so where an element in a combination method claim cannot be recited as a step for performing a specified function, Section 112(f) cannot apply. *See O.I. Corp.*, 115 F.3d at 1583; *see Cardiac Pacemakers*, 381 F.3d at 1381–82 (holding that the clause "determining a condition of the heart from among a plurality of conditions of the heart" did not implicate Section 112(f) because it was simply a step, and "[m]ethod claims necessarily recite the steps of the method"); *EBS Dealing Resources, Inc. v. Intercontinental Exchange, Inc.*, 379 F. Supp. 521, 529 (S.D.N.Y. July 27, 2005) (finding claim terms beginning with the verbs "administering" and

"deriving" to be "steps without functions" which were part of the "how" of the claim's ultimate function). Accordingly, Section 112(f) does not apply to Claim Term #2 because "knotlessly secured" is not functional language, nor is it clearly an independent step in the asserted method.

ii. Whether Section 112(f) Applies to Disputed Claim Term #4

Next the Court turns to Claim Term #4, which states, "cinching . . . into place . . . by applying traction." The full text of the disputed claim term, as it appears in claim 10 of the '686 Patent provides, "A method of ankle syndesmosis repair, comprising: . . . *cinching* a second fixation device *into place* against the bone plate *by applying traction* to a portion of an adjustable loop connected to the first fixation device and the second fixation device." (Doc. 54-5 at 23.)

Here, unlike in the disputed claim term above, functional language is present. As a verb ending in "-ing", "cinching" is clearly susceptible to interpretation as a function. *See Seal-Flex*, 172 F.3d at 849. Further, cinching "corresponds to *what* the claim element ultimately accomplishes in relationship to what the other elements of the claim and the claim as a whole accomplish" insofar as part of what is accomplished in Claim 10 is that a second fixation device is *cinched* into place against the bone plate. *See id.*; (Doc. 54-5 at 23.)

Having determined that this claim has the appearance of a step-plus-function, the Court next looks to whether an act is recited. *See Masco*, 303 F.3d at 1327. Given that "[a]cts . . . correspond to *how* the function is accomplished (i.e., to the implementation of the steps of the process)"—*see O.I. Corp.*, 115 F.3d at 1583;

see also Neurografix, 2012 WL 8281409, at *5–6—"applying traction" seems to be an act insofar as it corresponds to how the specified function of "cinching a second fixation device into place" is accomplished. *See Dynamic Digital*, 2016 WL 7444569, at *12–13 (assessing the claim term "displacing selected areas of said original 2D image by a determined amount and direction to thereby generate stretched images" and finding that "'displacing selected areas of said original 2D image by a determined amount and direction' constituted an act to perform the function of 'generat[ing] stretched images'" such that the claim was not a step-plus-function governed by Section 112(f)). This relationship between "applying traction" and "cinching a second fixation device" mirrors the distinction between underlying functions and acts outlined by Judge Rader in *Seal-Flex* in that the latter is the underlying function accomplished by the act of applying traction. Applying traction is therefore a specific act, which should indicate presumptively that the claim term is not a step-plus-function without acts. *See O.I. Corp.*, 115 F.3d at 1583.

Defendants assert that the claim term does not recite an act because it is unclear from the language of the claim how "cinching . . . into place . . . by applying traction" is accomplished. (*See* Doc. 56 at 26–27.) Specifically, Defendants argue that a POSA would not understand how knotless cinching would be achieved via the application of traction because "[a]pplying traction to a portion of an adjustable loop does not sufficiently perform knotless cinching as no traction is applied to any portion of the adjustable loop." (*Id.* at 27.) But *Masco* does not state that a claim reciting a function must also recite all of the acts required to perform that function.

See Masco, 303 F.3d at 1327 (explaining that where a method claim "does not contain the term 'steps for,' a limitation of that claim cannot be construed as a step-plus-function limitation without a showing that the limitation contains *no act*") (emphasis added). Nor does *Masco* require that "a claim reciting a function must also recite acts sufficient to perform that function." *Rensselaer Polytechnic Inst. v. Amazon.com, Inc.*, No. 118CV549BKSTWD, 2022 WL 819231, at *2 (N.D.N.Y. Mar. 18, 2022). Regardless, a clear instruction on how "applying traction" works to effect "cinching . . . into place" is found in Claim 15 of the '686 Patent, which states, "wherein cinching the second fixation device includes: applying the traction to a free strand of the adjustable loop such that a length of the adjustable loop is reduced and the first fixation device and the second fixation device are moved closer together." (Doc. 54-5 at 23.) Therefore, upon reading Claim 10's dependent claims, the Court is unconvinced that a POSA would not understand how applying traction could accomplish cinching.

Thus, given that the plain language of the referenced claims indicate that "applying traction" is an act involved in performing "cinching . . . into place[,]" the Court finds that the claim term is not a step-plus-function *without acts* subject to Section 112(f). *See Sage Prods. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427–28 (Fed. Cir. 1997) ("[W]here a claim recites a function, but then goes on to elaborate sufficient . . . acts within the claim itself to perform entirely the recited function, the claim is not in [step] plus function format.").

Accordingly, the Court finds that Section 112(f) does not apply to either

Claim #2 or Claim #4, and in the claim construction analysis detailed below, the Court will only address Defendants' alternatively proposed constructions with respect to these terms. The Court now turns to claim construction.

Disputed Claim Terms

Claim Term #1: " . . . at least one spliced section formed by splicing a strand of the [adjustable loop / flexible suture construct] through itself"

In this first disputed claim term, the parties appear to be in agreement that the wording of the claim limitation should not be changed. Instead, the parties' dispute concerns whether this claim term constitutes a step in a method of surgical repair or whether it merely describes the structure of the spliced sections of the adjustable loop / flexible suture construct used in the method of surgical repair. Arthrex argues that "splicing is not itself a step of the claimed method of surgical repair." (Doc. 55 at 8.) Defendants, meanwhile, argue that "splicing a strand of the adjustable loop through itself is a required method step recited in each of the asserted claims which are all method claims directed to knotless ankle syndesmosis repair." (Doc. 56 at 13.)

This claim term appears in claims 1, 10, and 19 of the '686 Patent as well as claims 1 and 16 of the '028 Patent. As recited in claim 1 of both the '686 and '028 Patents, the claim term provides:

> 1. A method of ankle syndesmosis repair, comprising:
>
> preparing a hole through a fibula and a tibia with a drill bit;
>
> passing a first fixation device through the hole until the first fixation device exits at a medial side of the tibia;

> flipping the first fixation device to an engagement position relative to the tibia; and
>
> positioning a second fixation device at a lateral side of the fibula,
>
> wherein the first fixation device and the second fixation device are knotlessly secured relative to the tibia and the fibula,
>
> wherein a flexible suture construct is connected to the first fixation device and the second fixation device, and wherein the flexible suture construct includes *at least one spliced section formed by splicing a strand of the flexible suture construct through itself*.

(Doc. 54-7 at 22–23; Doc. 54-5 at 22–23) (emphasis added).

The question for the Court, therefore, is whether "splicing a strand of flexible suture construct through itself" should be construed as an independent step. The Court finds that it should not. As is made clear in the spacing and punctuation of the claim language reflected above, four steps are clearly outlined: (1) preparing, (2) passing, (3), flipping, and (4) positioning. Each of these steps has its own dedicated paragraph, beginning with an unindented line on the page, and each of these steps concludes with a semicolon indicating that the various features of the step have been described in their entirety prior to the semicolon. It is also clear that the patentee intended that the only steps be the four steps above given the patentee's use of "and" before outlining the fourth and final "positioning" step.

The disputed claim term is therefore clearly a part of the step beginning with "positioning," as the two paragraphs beginning with "wherein" after the paragraph beginning with "positioning" follow a comma and do not begin with a verb in the present progressive form. Had the patentee wanted "splicing a strand of the flexible

suture construct through itself" to be a separate step, the patentee would have drafted the claim as such by moving "splicing" into its own paragraph and separating it from the "positioning" step by a semicolon. That the patentee did not draft Claim 1 this way is a clear indication to the Court that the patentee did not conceptualize "splicing" as a separate step. And as the Court reads it, the plain meaning of Claim 1 would not change if its final paragraph ended with "at least one spliced section" and "formed by splicing a strand of the flexible suture construct through itself" was omitted entirely.

Defendants cite to a number of cases to support the proposition that patented methods typically comprise a number of steps, and the method recited can only be understood by interpreting all of the asserted steps. (*See* Doc. 56 at 13–14 (citing *Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1373 (Fed. Cir. 2015) ("Claims must be interpreted with an eye toward giving effect to all terms in the claim") and *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) ("[A] claim to a process consists of a series of acts or steps.")).) But this is not disputed. Arthrex agrees that Claim 1 of the '028 and '686 Patents involves multiple steps; where Arthrex disagrees is that splicing is its own unique step. (*See* Doc. 55 at 8–9.) And Defendants cite to no case to support the theory that *any* act referenced in a particular limitation must be its own separate method step.

For example, in *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, to which Defendants cite, there was no dispute that the actions in question— "culturing," "disrupting," "oxidizing," and "extracting"—were their own steps. 790 F.3d 1298,

1305–06 (Fed. Cir. 2015). Rather, the question for the Federal Circuit was whether "the claim language require[d] that the recited steps be performed in order[;]" that is, did culturing have to come before disrupting, which had to come before oxidizing, which had to come before extracting. *Id.* at 1305. This, of course, is not the question presented here.

Instructively, the portion of the patent at issue in *Kaneka Corp.* recited the following:

> A process for producing on an industrial scale the oxidized coenzyme Q_{10} represented by the following formula:
>
> [Illustration omitted]
>
> which comprises *culturing* reduced coenzyme Q_{10} producing microorganisms in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient to obtain microbial cells containing reduced coenzyme Q_{10} at a ratio of not less than 70 mole % among the entire coenzymes Q_{10},
>
> *disrupting* the microbial cells to obtain reduced coenzyme Q_{10}; and
>
> *oxidizing* thus-obtained reduced coenzyme Q_{10} to oxidized coenzyme Q_{10} and then *extracting* the oxidized coenzyme Q_{10} by an organic solvent under an inert gas atmosphere.

Id. at 1301 (emphasis added).

Neither party requested that the Federal Circuit find that "obtain microbial cells" or "obtain reduced coenzyme Q_{10}" constituted independent steps, separate from "culturing" and "disrupting," even though the text of the patent claim makes clear that a POSA following the patented method could not move to the next step without these interstitial acts of obtaining the referenced cells or coenzymes. The Federal Circuit held that "because the claims affirmatively recite the step of

'oxidizing,' 'oxidizing' cannot be interpreted as doing nothing, or to simply allow oxidation to occur on its own. Nor can the other recited claim steps, such as culturing or disrupting, suffice as the active step resulting in oxidation." *Id.* Thus, applying the Federal Circuit's holding in *Kaneka Corp.* to this case would merely be to say that "preparing" must come before "passing," which must come before "flipping," which, in turn, must come before "positioning." It would not serve to say that "splicing" would be a step of its own.

Thus, without caselaw to support the argument that any action referenced in a patent claim must be an independent step by virtue of it being an action, and without support from the clear grammatical and editorial structure of the patent claim itself, the Court finds that the disputed claim term is not an independent step, and no further construction is required as to the claim term by mutual agreement of the parties.

Claim Term #2: "wherein the first fixation device and the second fixation device are knotlessly secured relative to the tibia and the fibula"

Arthrex asserts that this term means "wherein the first and second fixations devices are fastened together relative to the tibia and fibula, without knots holding the fixation devices in place." (Doc. 53-1 at 3.) Defendants suggest that "knotlessly secured" requires that "no knots can be used to secure the first and second fixation devices . . . no knots can be used during the securing step." (Doc. 56 at 20.)

The disputed claim term is found in Claim 1 of the '028 Patent, which recites "A method of ankle syndesmosis repair, comprising: . . . positioning a second

fixation device at a lateral side of the fibula *wherein the first fixation device and the second fixation device are knotlessly secured relative to the tibia and the fibula*." (Doc. 54-7 at 23.) Unlike the prior art, which "require[d] the tying of knots to secure the second (round) button against the surface of the lateral fibular cortex," the '028 Patent alleges to not "require[ ] the tying of knots to secure the second (round) button against the surface of the [bone]." (*Id.* at 19.) Instead, the suture material can be "thread[ed]" through the holes of the two buttons in a loop that is "flexible, adjustable, self-cinching, [and] knotless." (*Id.* at 20.) The term knotlessly, in the '028 Patent, is therefore used to indicate that no knots are used to secure the fixation devices to the tibia and the fibula. The term "secured" is likewise used in the claim term in accordance with its plain and ordinary meaning, indicating the manner in which the buttons are positioned on the bones. Nothing in the context of the '028 Patent suggests that either "knotlessly" or "secured" should be understood otherwise.

Based on the foregoing, the Court finds that Arthrex's proposed construction merely reformulates the claim in a way that may cause further inconsistencies. For example, Arthrex adds the phrase "fastened together" to the claim term, but this phrase is used nowhere else in the '028 Patent. Adding this phrase will allow more ambiguity to creep into the claim term as "fasten[ed] together" references a relationship between the two buttons that is not evidently clear from the claim term as it is currently written. That is, the claim term does not say that the first fixation device and the second fixation device are knotlessly secured *to each other* relative to

the tibia and the fibula. Thus, importing the term "together" may serve to confuse matters, while the term "fastened" is merely a synonym of "secured."

Here, the plain and ordinary meaning of the terms "knotlessly" and "secured" are clear within the context of the claim. *See Phillips*, 415 F.3d at 1314 (explaining that "the context in which a term is used in the asserted claim can be highly instructive"); *see Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1322 (Fed. Cir. 2016) (holding that it would be unwarranted to reshape claims during claim construction when the claims "leave little doubt as to what was intended"). Given that the Federal Circuit has advised that there is a "heavy presumption" that claim terms are given their ordinary and customary meaning to a POSA, the Court finds Arthrex's proposed construction is unnecessary. *See, e.g.*, *Mass. Inst. of Tech. v. Shire Pharm., Inc.*, 839 F.3d 1111, 1118 (Fed. Cir. 2016); *see also Medgraph, Inc. v. Medtronic, Inc.*, 843 F.3d 942, 950 (Fed. Cir. 2016) (declining to change the plain and ordinary meaning of the word "and" "[b]ecause the [patent's] written description does not compel a disjunctive construction"). Absent lexicography or disavowal, however, courts "do not depart from the plain meaning of the claims." *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016). Thus, the Court declines to adopt Arthrex's proposed construction.

Defendants' proposed construction is also flawed because Defendants appear to improperly add limitations to the claim term. As noted above, Defendants suggest that "knotlessly secured" should mean "no knots can be used to secure the first and second fixation devices." (Doc. 56 at 20; Doc. 58 at 17.) But this proposed

construction complicates matters by adding the phrase "used" which might convey that no knots whatsoever may be employed in the process of ankle syndesmosis repair, not that no knots hold the fixation devices in place. Adopting this proposed limitation might enable a would-be infringer to evade the '028 Patent's claims simply by having a knot somewhere in its suture—either in the loop, the pull-through suture, or otherwise. Neither the claim term itself, nor the specification state this limitation, however. In fact, the claim term explicitly hedges its reference to knotlessness with the clause "relative to the tibia and fibula" indicating that the tying of knots elsewhere in the flexible suture material is not necessarily precluded. (*See, e.g.*, Doc. 54-7 at 23.) Thus, the Court cannot adopt Defendants' proposed construction either. *See Cox Commc'ns Inc. v. Sprint Commc'ns Co. L.P.*, No. CV-12-487-SLR, 2017 WL 2106126, at *4 n.13 (D. Del. May 15, 2017) (declining to adopt a proposed construction where the "proposal add[ed] limitations not found in the claim or required by the specification"). Accordingly, the Court finds that Claim Term #2 is to be given its plain and ordinary meaning, and no further construction is required.

Claim Term #3: "a free strand"

Arthrex contends that "a free strand" should be constructed as "an end portion of a strand." (Doc. 53-1 at 4.) Defendants argue that the asserted claims require "a strand" for splicing and separately "a free strand" for applying traction. (*Id.*) Thus, per Defendants, the "free strand" is "a separate and different strand than the strand of the adjustable loop that is spliced through itself." (*Id.*) The

Court therefore must determine whether the "free strand" referenced in the claim term refers to a particular portion of the strand—namely, the portion of the strand that is not already spliced through itself—or whether it merely refers to any end portion of the strand.

The term "a free strand" is utilized four times throughout the claims made in the '686 Patent in claims 7, 15, and 19. (*See* Doc. 54-5 at 23.) Each time the term is used, it pertains to "tightening" or "cinching." (*See id.*) Claim 7 of the '686 Patent, for example, recites "tightening the second fixation device down on the lateral side of the fibula by applying traction to *a free strand* of the adjustable loop that is connected to each of the first fixation device and the second fixation device." (*Id.*) And claim 19 provides, "cinching a round fixation device into place within a second opening of the titanium bone plate by applying traction to *a free strand* of an adjustable loop." (*Id.*) "A free strand" is also used in claim 8 of the '028 Patent to describe the method "wherein positioning the second fixation device includes: applying traction to *a free strand* of the strand of the flexible suture construct." (Doc. 54-7 at 23.)

The use of the term "a free strand" in the '028 Patent is particularly instructive because the '028 Patent discloses "a free strand *of the strand*," indicating that there is a single strand in use and the free strand in question is a portion of the strand. This is made clear in Figures 5, 8, 9, 15, and 21 of the '028 and '686 Patents where the single strand, with two free strands that form part of the strand, is demonstrated. Figure 5 is shown below to illustrate the issue of the unitary strand.

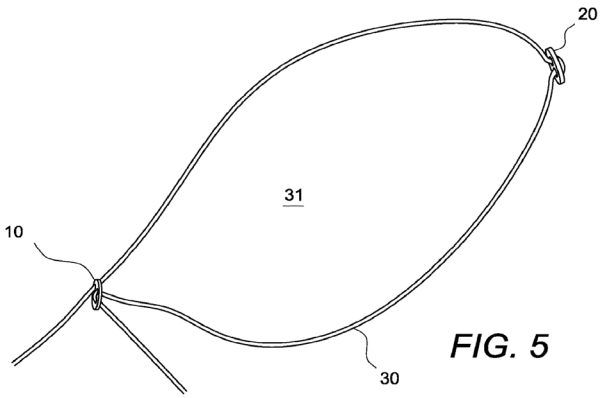

FIG. 5

(*Id.* at 6.)

In light of this compelling intrinsic evidence, the Court finds that Arthrex's construction clarifies the disputed limitation, while Defendants' construction creates the impression that there are two distinct strands rather than one single strand with two ends. Accordingly, the Court adopts Arthrex's proposed construction.

Claim Term #4: "cinching . . . into place . . . by applying traction"

Arthrex argues that this disputed term should be construed as "tightening . . . into place . . . by applying traction." (Doc. 55 at 21.) Defendants contend that "cinching" means "knotless positioning," and if it does not mean "positioning," whatever action is taking place must be knotless. (Doc. 56 at 24–25.) Claim Term #4 appears in claims 10, 15, 16, and 19 of the '686 Patent. (*See* Doc. 54-5 at 23.)

Based on the parties' proposed constructions, the Court must determine the meaning of "cinching" as it is used in the '686 Patent. The specification only mentions the term "cinching" once and states that "the first button of the construct is passed . . . through drill holes passing through the fibula and tibia bones . . . and the second . . . button is then tightened against the lateral fibular cortex simply by

cinching the adjustable construct (instead of tying knots)." (*Id.* at 22.) The Court will construe cinching to have its plain and ordinary meaning given that there is no indication that the patentee intended cinching to have its own unique meaning or that the patentee disavowed the plain and ordinary meaning of cinching. *See Phillips*, 415 F.3d at 1316.

To determine the ordinary meaning of a claim term, courts are instructed to look to the relevant dictionary definitions. *See E-Pass Tech., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1367 (Fed. Cir. 2003) (using Merriam-Webster's Collegiate Dictionary, Random House Webster's Unabridged Dictionary, and the Oxford English Dictionary to determine the ordinary meaning of the term "card"). Cinch, as a transitive verb, is defined to mean "to fasten (something, such as a belt or strap) tightly" or "to fix (a saddle, etc.) securely by means of a girth." *Cinch*, *Merriam-Webster Dictionary Online* https://www.merriam-webster.com/dictionary/cinch (last accessed June 30, 2023); *Cinch*, *Oxford English Dictionary Online* https://www.oed.com/view/Entry/33049?rskey=LnuoN1&result=2#eid (last accessed June 30, 2023). These two definitions indicate that cinching means fastening or fixing something tightly or securely.

With these definitions in mind, Arthrex's proposed construction, wherein cinching means "tightening," and Defendants' proposed construction wherein cinching means "positioning," both seem to slightly miss the mark. Cinching does not *just* signify tightening, nor does it *just* represent positioning. Instead, cinching

appears to involve *both* the process of fastening or fixing to the object *and* the process of tightening or securing the material that is being cinched around the object or relative to another object.[2] This distinction is clear from the specification, which states, "the second (round) button is then *tightened against* the lateral fibular cortex simply by *cinching* the adjustable construct (instead of tying knots)" which indicates that while cinching involves tightening, and positioning—given that the tightening serves to place the button against the lateral fibular cortex—it is importantly discrete from both tightening and positioning. (Doc. 54-5 at 22.)

Thus, both Arthrex and Defendants miss some element of the cinching process in their proposed constructions; Arthrex misses the fastening or fixing, while Defendants miss the tightening or securing. Accordingly, the Court declines to adopt either proposed construction. *See U.S. Surgical v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("The *Markman* decisions do not hold that the trial judge must repeat or restate every claim term . . . . Claim construction is a matter of resolution of disputed meanings . . . for use in the determination of infringement. It is not an obligatory exercise in redundancy.").

Claim Term #5: "a portion of an adjustable loop"

Arthrex argues that no construction is required as to this limitation. (Doc. 55 at 25.) Defendants, however, argue that the portion of the loop referred to "must

[2] To illustrate, the archetypal example of cinching refers to the process of preparing a saddle on a horse. *See Cinch* OXFORD ENGLISH DICTIONARY ONLINE https://www.oed.com/view/Entry/33049?rskey=LnuoN1&result=2#eid (last accessed June 30, 2023) (providing the following examples of cinch: "the saddles are cinched tighter"; "saddles were cinched on waiting horses").

mean the two free ends of suture of the adjustable loop." (Doc. 56 at 29–30.)

"A portion of an adjustable loop" appears in claim 10 of the '686 Patent. Specifically, claim 10 discloses, "[a] method of ankle syndesmosis repair, comprising: . . . cinching a second fixation device into place against the bone plate by applying traction to *a portion of an adjustable loop* connected to the first fixation device and the second fixation device." (Doc. 54-5 at 23.) Defendants argue that because the only adjustable loop described by the '686 Patent requires "two free ends extending from two separate eyesplices of the adjustable loop," it must be the case that the portion of the adjustable loop to which traction is applied refers to the two free ends of the suture of the adjustable loop. (Doc. 56 at 29.)

Figures 17 through 20 in the '686 Patent are instructive as they provide the only account of the process by which the loop is tightened and tension between the buttons is adjusted so as to secure the buttons into place. (Doc. 54-5 at 12.) The relevant specification provides that traction is applied in three ways in three different places. Specifically,

> Once the first, oblong button 20 has exited the medial tibia 90, the angle of *traction on the pull-through suture* 86, 87 is changed and *counter-traction is exerted on the loop* 33, in order to flip (pivot) and engage the oblong button 20 against the medial tibial cortex . . . The trailing or second, round button 10 is tightened down on the lateral side by further *traction on the free ends of the suture* 30 to tighten the adjustable, flexible loop 33 and adjust the tension between the two buttons.

(*Id.* at 22) (emphasis added).

From this account of the single preferred embodiment offered by the patentee, the diagrams should illustrate that whichever features or materials are

illustrated at points 86, 87, 30 and 33 are the portion(s) of the adjustable loop on which traction is exerted.

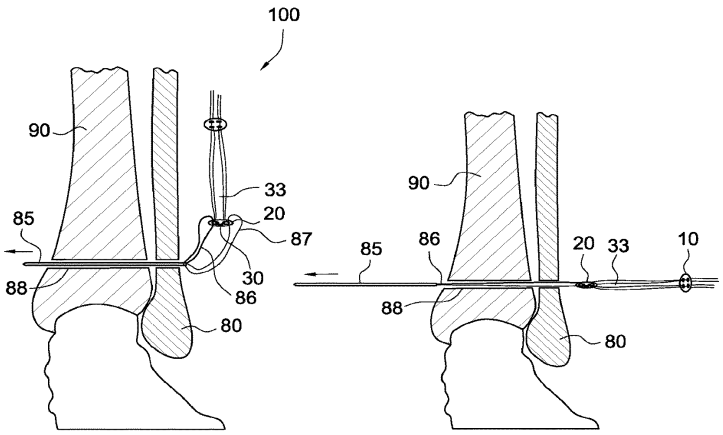

FIG. 17 FIG. 18

(*Id.* at 12.) While Defendants argue that the "portion of an adjustable loop" on which—or to which—traction is applied must signify the two free ends of the suture, indicated at 30, the specification and the illustrations in Figures 17 and 18 appear to indicate that traction is applied not just to the two free ends, but also to the "knotless, adjustable flexible loop" at 33 and the "pull-through suture" at 86 and 87. (*See id.* at 21–22.) Thus, to say that traction is applied solely to the "free ends" appears to construe "portion of an adjustable loop" in too narrow a manner given that traction is also applied to the "pull-through suture" and the "knotless, adjustable flexible loop" as a whole. This makes sense considering that "cinching" appears to involve tightening the entire adjustable construct. (*See id.* at 23.)

Accordingly, Defendants' proposed construction is not proper. While it is true that a claim must be read in view of the specification, it is also true that a court may not read a limitation into a claim from the specification. *See Liebel-Flarsheim*

Co. v. Medrad, Inc., 358 F.3d 898, 904–05 (Fed. Cir. 2004) (describing the "fine line" and "inherent tension" presented by these rules of construction). Specifically, "particular embodiments appearing in the written description will not be used to limit claim language that has broader effect." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004). Here, the claim language referenced clearly has broader effect, in that traction is applied to the "knotless, adjustable flexible loop," the "pull-through suture," and the "free ends," but Defendants offer only a narrow construction that references only one of these three areas. Nor do Defendants offer any evidence that the three above terms are synonymous or interchangeable such that reference to only one—"the free ends"—would effectively encompass them all.

Given the inadequacies of Defendants' proposed construction, the Court declines to adopt Defendants' proposed construction and finds that, as Arthrex has argued, no further construction is needed. Due to the apparent ambiguities of this claim term, however, the Court will be open to requests for supplemental claim construction as to this term, once further discovery is completed.

Claim Term #6: "flexible suture construct"

Arthrex posits that "flexible suture construct" means "an arrangement or construction of flexible suture." (Doc. 53-1 at 6.) Defendants assert that the term refers to "the construct disclosed in the specification formed of a pair of buttons connected by a flexible, knotless, adjustable loop that includes a flexible material with two adjustable eyesplices." (*Id.*) Based on the proposed constructions, the

question for the Court is whether "flexible suture construct" includes all of the elements that Defendants assert—buttons and eyesplices included—or whether the patentee intended the term to refer solely to flexible suture material.

Here, "[f]lexible suture construct" appears 10 times in the '028 Patent in Claims 1, 7, 8, 9, 16, and 18. (Doc. 54-7 at 23.) Claim 1 appears to be the most thorough account of the "flexible suture construct," stating that "a flexible suture construct is connected to the first fixation device and the second fixation device, and wherein the flexible suture construct includes at least one spliced section formed by splicing a strand of the flexible suture construct through itself." (*Id.*) From the language of this claim alone, it seems clear that "flexible suture construct" does not include the pair of buttons, as Defendants contend, because the flexible suture construct is said to be *connected* to the fixation devices. If the flexible suture construct was comprised of those fixation devices, announcing that it was *connected* to them would be redundant and misleading. *See Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 848 (Fed. Cir. 2006) (explaining "the terms 'engaging' and 'sealing' are both expressly recited in the claim and therefore 'engaging' cannot mean the same thing as 'sealing,' and thus each term is presumed to have a distinct meaning").

Claim 7 meanwhile provides for "applying traction to the pull-through suture while applying counter-traction to the flexible suture construct," which once again indicates that the flexible suture construct does not include every part of the reconstruction system for ankle syndesmosis repair, otherwise it could not receive

countertraction. (Doc. 54-7 at 23.) That is, if the flexible suture construct and the pull-through sutures were one in the same, countertraction would be an impossibility as there would only be traction. Thus, Defendants' proposed construction appears to elide the distinctions between the various sutures referenced in the patent so as to encompass all of the referenced suture forms into the "flexible suture construct." This interpretation ignores the modifiers that the patentee clearly put on each type of suture, which is inconsistent with predominant claim construction methods. *See Innova/Pure Water, Inc.*, 381 F.3d at 1119–20 (Fed. Cir. 2004) (holding that a party's claim "interpretation largely reads the term 'operatively' out of the phrase 'operatively connected.' While not an absolute rule, all claim terms are presumed to have meaning in a claim").

Finally, the Court notes that the summary of the invention states, "[t]he present invention provides methods and reconstruction systems (an adjustable, self-locking knotless button/loop construct) for ankle syndesmosis with or without associated ankle fractures repair." (Doc. 54-7 at 19.) With this introductory sentence, the patentee signifies that all of the parts which Defendants seek to read into the claim term "flexible suture construct" are, in fact, known as the "reconstruction system." The term "reconstruction system" is used six times throughout the '028 Patent, each time encapsulating all of the materials utilized in the claim language. (*See, e.g.*, *id.* at 22.) For example, the patentee states, "Figs. 2-14 illustrate exemplary steps of a method of assembling the reconstruction system . . . with the following starting materials which are only exemplary . . . suture strand

30, needle with nitinol loop 40, round button 10, oblong button 20." (*Id.* at 20.) Thus, it seems that Defendants are conflating the "flexible suture construct" with the "reconstruction system" when the language of the patent suggests that the entities are distinct. This approach runs counter to the patentee's intentions, however, and is therefore inappropriate. *See Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004) (explaining that the patentee should ordinarily receive the benefit of "the full scope of its claim language"). Accordingly, the Court declines to adopt Defendants' proposed construction.

Arthrex's proposed construction—"an arrangement or construction of flexible suture"—appears to much more closely mirror the patentee's use of the term. And given that the term "construct" is used several times throughout the patent without specific reference to the "flexible suture construct," and in a manner that seems distinct from the "flexible suture construct," the Court finds that Arthrex's proposed construction offers a helpful means of clarifying these inconsistencies and avoiding the ambiguous term "construct." Accordingly, the Court adopts Arthrex's proposed construction.

CLAIM CONSTRUCTION CHART

	Disputed Claim Term	**Court's Construction**
Claim Term #1	"…at least one spliced section formed by splicing a strand of the [adjustable loop / flexible suture construct] through itself"	No construction required and not a method step.
Claim Term #2	"wherein the first fixation device and the second fixation device are knotlessly secured relative to the tibia and the fibula"	No construction required, and Section 112(f) does not apply.
Claim Term #3	"a free strand"	"an end portion of a strand"

Claim Term #4	"cinching…into place…by applying traction"	No construction required, and Section 112(f) does not apply.
Claim Term #5	"a portion of an adjustable loop"	No construction required.
Claim Term #6	"flexible suture construct"	"an arrangement or construction of flexible suture"

CONCLUSION

The claim terms at issue will be construed for the jury and for all other purposes in a manner consistent with the above rulings of the Court. On or before July 14, 2023, the parties are **DIRECTED** to submit a Joint Proposed Schedule for the conclusion of fact discovery, expert discovery, and dispositive motions.

ORDERED at Fort Myers, Florida on June 30, 2023.

JOHN L. BADALAMENTI
UNITED STATES DISTRICT JUDGE